K132736
Page 1 of 3

MAR 1 1 2014

510 (k) Summary
21 CFR 807.92

Accuro 3000 Ultrasound System

General Provisions	Submitter Name: Submitter Address:	Rivanna Medical, LLC 1304 Stonegate Court Crozet, VA 22932
	Contact Person:	Will Mauldin, PhD Chief Technology Officer (t) 828.612.8191 (e) wmauldin@rivannamedical.com
	Date of Preparation:	3 February 2014
Subject Device	Trade Name:	Accuro 3000 Ultrasound System
	Classification Name:	IYO21 CFR892.1560 Ultrasonic Pulsed Echo system ITX21 CFR892.1570 Diagnostic Ultrasound Transducers
Predicate Device	Trade Name:	BladderScan BVI 9400 Ultrasound System
	Classification Name:	IYO21 CFR892.1560 Ultrasonic Pulsed Echo System ITX21 CFR892.1570 Diagnostic Ultrasound Transducers
	Premarket Notification:	K071217, May 17th 2004
	Manufacturer:	Verathon, Inc.
Predicate Device	Trade Name:	Voyager Ultrasound Imaging System
	Classification Name:	IYO21 CFR892.1560 Ultrasonic Pulsed Echo System ITX21 CFR892.1570 Diagnostic Ultrasound Transducers
	Premarket Notification:	K050551, March 22nd 2005
	Manufacturer:	Ardent, Inc

Predicate Device	Trade Name:	MobiUS Ultrasound Imaging System
	Classification Name:	IYO21 CFR892.1560 Ultrasonic Pulsed Echo System ITX21 CFR892.1570 Diagnostic Ultrasound Transducers
	Premarket Notification:	K102153, January 20th 2011
	Manufacturer:	Mobisante, Inc.
Device Description	The Accuro 3000 Ultrasound Imaging Device is a hand-held device that features real-time B-mode ultrasound imaging only. Additional features include a compact size and a simple user interface.	
Indications for Use	The Accuro 3000 ultrasound scanner is intended for diagnostic ultrasound imaging of the human body in the following clinical applications: Abdominal, Musculoskeletal (Conventional and superficial), Cardiac, Peripheral vascular. A typical examination using the Accuro 3000 is guidance of neuraxial anesthesia.	
Technological Characteristics	Technological characteristics of the Accuro 3000 are equivalent with respect to the basic design and function of the predicate devices. The Accuro 3000 has no technologies, features, or indications for use not commonly used in the practice of diagnostic ultrasound.	
Safety & Performance Tests	Verification and Validation activities were designed and performed to demonstrate that the Accuro 3000 met pre-determined performance specifications. The following standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device:	

IEC 60601-1:1988/91/95, Medical Electrical Equipment – Part 1: General Requirements for Safety
IEC 60601-1-1:2000, Medical Electrical Equipment – Part 1-1: General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems
IEC 60601-1-2:2007, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
IEC 60601 1-4:2000, Medical Electrical Equipment – Part 1-4: General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Systems
IEC 60601-2-37:2008, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
UL 60601-1:2003, Medical Electrical Equipment, Part 1: General Requirements for Safety
NEMA UD-2:2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
NEMA UD-3:2004, Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject Accuro 3000,

met the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, principles of operation and indications for use to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 11, 2014

Rivanna Medical, LLC
% William Mauldin, Ph.D.
Chief Technology Officer
1304 Stonegate Court
CROZET VA 22932

Re: K132736
Trade/Device Name: Accuro 3000 Ultrasound Scanner
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: February 12 2014
Received: February 18, 2014

Dear Dr. Mauldin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132736

Device Name
Accuro 3000 Ultrasound System

Indications for Use *(Describe)*
The Accuro 3000 ultrasound scanner is intended for diagnostic ultrasound imaging of the human body in the following clinical applications: Abdominal, Musculoskeletal (Conventional and superficial), Cardiac, Peripheral vascular. A typical examination using the Accuro 3000 is guidance of neuraxial anesthesia.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara

Diagnostic Ultrasound Indications For Use

System: Accuro 3000
Transducer: _____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N						
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**	N						
	Musculo-skeletal **(Superficial)**	N						
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	N						
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N						
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging